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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,582	11/06/2000	Frank M. Jordan	Immusonic-004	9647

7590 05/29/2003

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/29/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/707,582

Applicant(s)

JORDAN ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-17 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6 and 18-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-24 are pending.
2. Claims 7-17 and 22-24 are elected and rejected.
3. Claims 1-6 and 18-21 are non-elected and withdrawn from consideration.

Response to Arguments

4. Applicant's arguments with respect to claims 7-17 and 22-24 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

5. This application contains claims 1-6 and 18-21 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7 and 9-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to methods of expressing an increased number of B7 molecules on the surface of an antigen presenting cell to enhance or regulate an immune system comprising the steps of: obtaining an *upregulating agent* to an organism; and, allowing an up regulation of B7 molecules on a cell whereby an expression of the B7 molecules allows reaction with an effector cell, the reaction with the armed effector cell potentiating an immune response. These claims fail to meet the written description requirement for the following reasons. The term an *upregulating agent* is written functionally. There is insufficient descriptive support for the functional term *upregulating agent* in the instant specification. In addition, the instant specification does not describe what is meant by the functional characteristics of being known as an *upregulating agent*. Structural identifying characteristics of the term *upregulating agent* are not disclosed. There is no evidence that there is any per se structure/function relationship between the disclosed term of an *upregulating agent* and any others that might be found using the claimed method. Furthermore, there is no support that the particularly disclosed term of an *upregulating agent* is represented by the sole examples of beta-1,3-glucans and beta-1,6-glucans. The specification does; however, provide an adequate written description of the *upregulating agent* of beta-1,3-glucans and beta-1,6-glucans. There is no description of an actual reduction to practice, each step of the claimed method to show that the applicant was in possession of the claimed invention. Therefore, the claim fails to

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comply with the written description requirement. In the absence of some understanding of the term of the functional term of *upregulating agent* other than adequately described beta-1,3-glucans and beta-1,6-glucans, the artisan would not have accepted that the applicant was in possession of the claimed method as currently written.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7, 8, 13, 22, and 23 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Rorstad et al. of U.S. Patent No. 5,401,727. Rorstad et al. are directed to a process for stimulating the immune system and/or enhancing the resistance by administering immunostimulatory compounds, such as glucans. In fact, Rorstad et al. teach that the specific glucans that have beta-1,3- glycosidic bonds and beta-1,6 glycosidic bonds are immunostimulatory compounds that act are used to enhance the resistance of a subject in need thereof, (see columns 1 and 2). Rorstad et al. teach that these immunostimulatory compounds of glucans that have beta-1,3- glycosidic bonds and beta-1,6 glycosidic bonds can be administered in a variety of routes such as enterally or parenterally as well as listing various pharmaceutically acceptable carriers

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for these pharmaceutical preparations with the immunostimulatory compounds of glucans that have beta-1,3- glycosidic bonds and beta-1,6 glycosidic bonds, (see columns 7 and 8).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The rejection of claims 7-17 under 35 U.S.C. 103(a) as being unpatentable over Costello et al. is withdrawn in response to the amendment of January 4, 2003.

12. Claims 7-17 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rorstad et al. of U.S. Patent No. 5,401,727 in view of Ostrand-Rosenberg et al. of U.S. Patent No. 5,858,776. Rorstad et al. are directed to a process for stimulating the immune system and/or enhancing the resistance by administering immunostimulatory compounds, such as glucans. In fact, Rorstad et al. teach that the specific glucans that have beta-1,3 glycosidic bonds and beta-1,6 glycosidic bonds are immunostimulatory compounds that act are used to enhance the resistance of a subject in need thereof, (see columns 1 and 2). Rorstad et al. teach that these immunostimulatory compounds of glucans that have beta-1,3 glycosidic bonds and

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beta-1,6 glycosidic bonds can be administered in a variety of routes such as enterally or parenterally as well as listing various pharmaceutically acceptable carriers for these pharmaceutical preparations with the immunostimulatory compounds of glucans that have beta-1,3- glycosidic bonds and beta-1,6 glycosidic bonds, (see columns 7 and 8).

13. The prior art reference of Ostrand-Rosenberg et al. teach that T cell activation requires an antigen-specific signal, often called a primary activation signal, which results from stimulation of a T cell receptor present on the surface of the T cell. Ostrand-Rosenberg et al. also disclose that this antigen-specific signal is usually in the form of an antigenic peptide bound either to a major histocompatibility complex (MHC) class I protein or an MHC class II protein present on the surface of an antigen present cell (APC). Ostrand-Rosenberg et al. further teach that these class II molecules are found on a limited number of cell types, such as B cells, monocytes/macrophages, and dendritic cells. In addition to an antigen-specific primary activation signal, T cells also require a second, non-antigen specific, signal to induce full T cell proliferation and/or cytokine production, which is known as costimulation. The costimulatory molecule is triggered by a molecule on the surface of the APC, just like the antigen-specific signal. Ostrand-Rosenberg et al. further teach that the B lymphocyte antigen B7 is a costimulatory molecule. In addition, Ostrand-Rosenberg et al. further teach that B-lymphocytes, in particular B7, are costimulatory molecules that activate antigen-presenting cells. Accordingly, it would have been obvious one having ordinary skill in the art to select any other member of the B lymphocyte family, especially when the prior art reference of Ostrand-Rosenberg et al. disclose that B lymphocytes, in particular B7,

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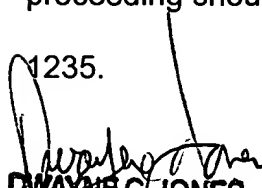
are costimulatory molecules that activate antigen presenting cells, (see column 1). In fact, Rorstad et al. do teach of a variety of carriers and modes of administration, (see columns 7 and 8). The determination of a dosage and mode of administration is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug. Hence, the combination of references make obvious the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
May 28, 2003